

REMARKS

Status of the Claims

Claims 17, 18 and 28 have been amended to clarify that, in the secondary standard for calibrating an instrument for subsequent measurement of an analyte sample, there is a medium for the secondary standard (which includes one or more viscosity changing polymers and at least one dye) that is different than the medium of the analyte sample measurement.

Support for this amendment can be found, for example, in the Example on page 14 of the specification. In that Example the medium of the secondary sample is set forth on line 18 (98 g of Polyphobe® TR116). The medium of the analyte sample is set forth on line 10 (TRIS/HCl buffer at pH8). These mediums are different. No new matter has been added by this amendment

Examiner Requested Documents

The Examiner has requested documents relating to secondary standards, including the references listed on page 4 of the specification. In response to this request, an Information Disclosure Statement accompanies this Amendment.

Rejections Under 35 U.S.C. § 112, first paragraph

Claims 17-31 stand rejected as failing to comply with the written description requirement. The Examiner states that there is no basis for the recitation "wherein the concentration of the dye is adjusted such that the fluorescent signal of the dye in the secondary standard after gelling the mixture is at least approximately equal to the fluorescent signal of a known concentration of the dye under the conditions of the analyte sample measurement."

The Examiner notes the following passage of the specification:

"The dyes real concentration is adjusted to yield fluorescence intensities equaling that of a primary standard, 100 nM CyC in TRIS/HCL buffer . .
."

(Specification, page 14, lines 9-10). Applicants also note the following passage:

"The amount of the dye in this [secondary] standard should be such that the resulting signal is equivalent to a primary standard, at 10 nM sodium fluorescein . . ."

(Specification, page 14, lines 9-10). The definition of a primary standard is also set forth:

"A primary or ideal standard is essentially identical to the analyte sample, except that it contains a known amount of the active compound."

Nevertheless, the Examiner states that the instant claim limitation is not equivalent to the statements in the specification. It appears as if the Examiner objects to the "*approximately* equal" language in the claims.

This rejection is respectfully traversed. The specification explains that a secondary standard is composed of a material that *closely* mimics the characteristics of a primary standard (page 5, lines 19-20). A person of ordinary skill would understand that a secondary standard cannot always have a fluorescence intensity that *exactly* equals the fluorescent signal of a known concentration of the dye under the conditions of the analyte sample measurement, i.e., known concentrations of the dye in the primary standard. Instead, the secondary standard, in practice, *closely* mimics or approximates the primary standard.

Based on the above disclosure of a secondary standard, and the passage cited by the Examiner exemplifying a secondary standard, one of ordinary skill can reasonably conclude that the inventor had possession of the claimed invention. See MPEP § 2163, *citing, Moba, B.V. v.*

Diamond Automation, Inc., 325 F.3d 1306, Fed. Cir. 2003. Applicants request that the rejection be withdrawn.

Rejections Under 35 U.S.C. §§ 102 and 103

Claims 17-23, 27 and 30-31 stand rejected as anticipated by Cote (U.S. Pat. No. 6,485,703). Claims 17-31 stand rejected as obvious over Cote in view of Little (U.S. Pat. No. 6,077,669).

The Examiner states that the sample described in Cote is a secondary standard because the detected component is not the analyte per se, although the detected component is influenced by the analyte. Applicant respectfully disagrees with this statement, as the a secondary standard has a medium that is different than the medium used in the course of obtaining non-calibration measurements.

The Examiner also states that "wherein the concentration of the dye is adjusted such that the fluorescent signal of the dye in the secondary standard after gelling the mixture is at least approximately equal to the fluorescent signal of a known concentration of the dye under the conditions of the analyte sample measurement" is met by any amount of dye used by Cote. The Examiner's apparent reasoning is that since Cote purportedly teaches a secondary standard, whenever one adds dye and determines its concentration in Cote, one necessarily adjusts the fluorescent signal of the dye such that it is equal to a known concentration of the dye under the conditions of the analyte sample measurement.

The Examiner has not addressed that the medium used in a secondary standard is more stable, and hence different than the medium used in determining the analyte of interest. The Examiner's position that Cote teaches a secondary standard in that the detected component is not the analyte is incorrect because the medium used in Cote contains the analyte of interest *under the conditions of the analyte sample measurement*. This is also the case in Little, which teaches the

concept of a primary standard, as opposed to a secondary standard (see, e.g., Little, column 8, lines 8-12).

Applicants have amended claims 17, 18 and 28 to clarify that the claims of the present application are directed to a *process* which calibrates an instrument with a secondary standard for subsequent measurement of an analyte sample in which the medium of the secondary standard is different from the medium used by the instrument for analyte sample measurement, i.e. the non-calibration measurements. This is not taught or suggested in the cited references, in which any calibration steps are performed in the same medium as the normal sample measurements.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

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Respectfully submitted,

By 

Jason C. Chumney

Registration No.: 54,781

DARBY & DARBY P.C.

P.O. Box 5257

New York, New York 10150-5257

(212) 527-7700

(212) 527-7701 (Fax)

Attorneys/Agents For Applicant